Remarks

Claims 95-102, 104, 108, 112, 116, 120-132, 138, 147, 151 and 168-397 are pending in the subject application. By this Amendment, Applicants have amended claims 95, 120, 127, 186, 205, 224, 251, 252, 271, 299, 300, 319, 347, 348 and 367 and canceled claims 98-102, 104, 108, 112, 116, 122, 123, 138, 242-244, 246-250, 291, 292, 294-298, 339, 340, 342-346, 398, 388 and 390-394. Certain claims have been amended to correct typographical errors noted in the previously pending claims. Support for the amendments and can be found throughout the subject specification and in the claims as originally filed. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 95-102, 104, 108, 112, 116, 120-132, 138, 147, 151 and 168-397 are currently before the Examiner (with claims 95-97, 120-121, 124-132, 147, 151, 168-241, 245-249, 251-290, 293, 299-338, 341, 347-386, 389, 395-397 reading on the elected invention). Favorable consideration of the pending claims is respectfully requested.

Applicants also wish to draw the Examiner's attention to a continuation application (U.S. Patent Application Serial No. 11/841,886, filed August 20, 2007) claiming the benefit of the subject application. Applicants note that a restriction requirement has been issued in that matter.

As an initial matter, Applicants gratefully acknowledge the Examiner's indication that claims 147 and 151 are objected to but would be allowable if rewritten into independent form to include the limitations of any base and intervening claims.

Applicants gratefully acknowledge the indication that the previous grounds of rejection have been withdrawn and that the Notice of Non-Responsive Amendment mailed on April 4, 2008 has been withdrawn. The remarks set forth in the Interview Summary Form are consistent with the substance of that interview.

Claims 95-97, 120-121, 124-132, 168-241, 245-249, 251-290, 293, 299-338, 341, 347-386, 389, and 395-397 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a mammal having diabetes comprising the administration of a pharmaceutically effective amount of an insulin sensitizer agent and a pharmaceutically effective amount of an FBPase inhibitor or prodrug or salt thereof, wherein said insulin sensitizer agent is troglitazone or rosiglitazone and wherein said FBPase inhibitor is Compound A, B, C, D, E, F, G, H, I, J or K, does not reasonably provide enablement for treating a mammal having diabetes comprising

the administration of a pharmaceutically effective with any compound of formula I or IA in combination with any insulin sensitizer agent. The Office Action further argues that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims and that undue experimentation is required to determine which compounds would be useful as an insulin sensitizer agent and/or FBPase inhibitor for which the instant invention is applicable and to determine which of these combinations would be useful in treating diabetes in a mammal. Finally, the Office Action argues that "only Compounds A-K (FBPase inhibitor) in combination with troglitazone or rosiglitazone (insulin sensitizer agent) were assessed, out of the numerous insulin sensitizer agents known in the art, not to mention the near infinite number of compounds and classes of compounds embraced by the instantly claimed formulae I and IA" (see Office Action at page 5).

When rejecting a claim under the enablement requirement of section 112, the examiner bears the "initial burden of setting forth a reasonable explanation as to why [he/she] believes that the scope of protection provided by [the] claim is not adequately enabled by the description of the invention provided in the specification." *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Additionally, the examiner must provide evidence or technical reasoning substantiating those doubts. *Id.*; and M.P.E.P Section 2164.04. As noted above, the Office Action seems to focus on the number of compounds that may be tested in combination with numerous insulin sensitizers known in the art. Applicants respectfully submit that this is insufficient for rejecting the claims as failing to comply with the enablement requirement of section 112 and that the Office Action fails to meet its initial burden for establishing that the claimed invention is not enabled and that the rejection should be withdrawn.

While Applicants remain of the position that the last Office Action failed to establish that the claimed invention was not enabled, Applicants provide the following additional arguments. As the Patent Office is aware, enablement is a legal determination of whether a patent enables one skilled in the art to make and use the claimed invention (*Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960, 220 U.S.P.Q. 592, 599 (Fed. Cir. 1983)) and is not precluded even if some experimentation is necessary. *Atlas Powder Co. v. E.I. Du Pont De Nemours & Co.*, 750 F.2d 1569, 1576, 224 U.S.P.Q. 409, 413 (Fed. Cir. 1984); *W.L. Gore and Associates v. Garlock, Inc.*, 721 F.2d 1540, 1556, 220 U.S.P.Q. 303,

315 (Fed. Cir. 1983). The Patent and Trademark Office Board of Patent Appeals and Interferences has also stated: "The test [for enablement] is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed". *Ex parte Jackson*, 217 U.S.P.Q. 804, 807 (1982); *see also Ex parte Erlich* 3 U.S.P.Q.2d 1011 (B.P.A.I. 1982) (observing that although a method might be "tedious and laborious," such experimentation is nevertheless "routine" defining "routine" experiments as those which use known methods in combination with the variables taught in the patent).

As noted above, "a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed". In this case (and as noted in the Office Action), an assay has been described for identifying other FBPase inhibitors. Thus, the as-filed specification clearly provides guidance as to how one skilled in the art was to screen for compounds having the ability to inhibit FBPase activity. Applicants further note that the as-filed specification provides guidance for both *in vitro* and *in vivo* assessment of the combined effects of the claimed compositions (see pages 242-261 of the as-filed specification) and animal models suitable for use in such assessments were known in the art (see pages 3, 21 and 130-131). Applicants further note that the as-filed specification teaches those insulin sensitizers suitable for use in the claimed methods (see pages 126-133). Thus, Applicants respectfully submit that the as-filed specification fully enables the claimed invention and that undue experimentation would not be required to practice the claimed invention.

Furthermore, the claims do not, as argued in the Office Action, define "some part of an invention in functional terms", rather, the claims recite a method of treating diabetes comprising the administration of an FBPase inhibitor having a chemical structure specifically defined in the claims. While a functional aspect of the claimed compounds as FBPase inhibitors is recited within the claims, the full chemical structure is also recited therein. Thus, it is clear that no portion of the

claimed methods recite "some part of the claimed invention in functional terms"; rather, the claimed invention is claimed as a chemical compound that has the recited biological activity.

Finally, Applicants note the Office Action argues that the compounds of Formulae I and IA do not share a common, substantial chemical core and that there is no discernable pattern as to which compounds would inhibit FBPase activity. In this regard, Applicants note that the as-filed application indicates that certain of the preferred claimed compounds bind to the AMP site of FBPase (see, for example, specification at page 26); thus, those skilled in the art would have had adequate knowledge as to the structures of compounds suitable for use in such a fashion and undue experimentation would not have been required to practice the claimed invention. Accordingly, reconsideration and withdrawal of the rejection of record is respectfully requested.

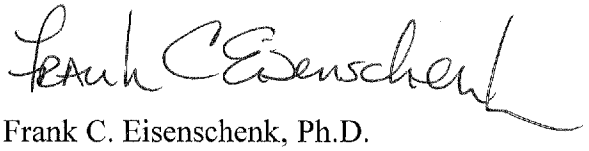
It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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